

**EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Walter Steinkraus on 1/2/07.

The application has been amended as follows:

Claim 29 is cancelled.

Claim 38, line 1 replace "claim 34" with "claim 30".

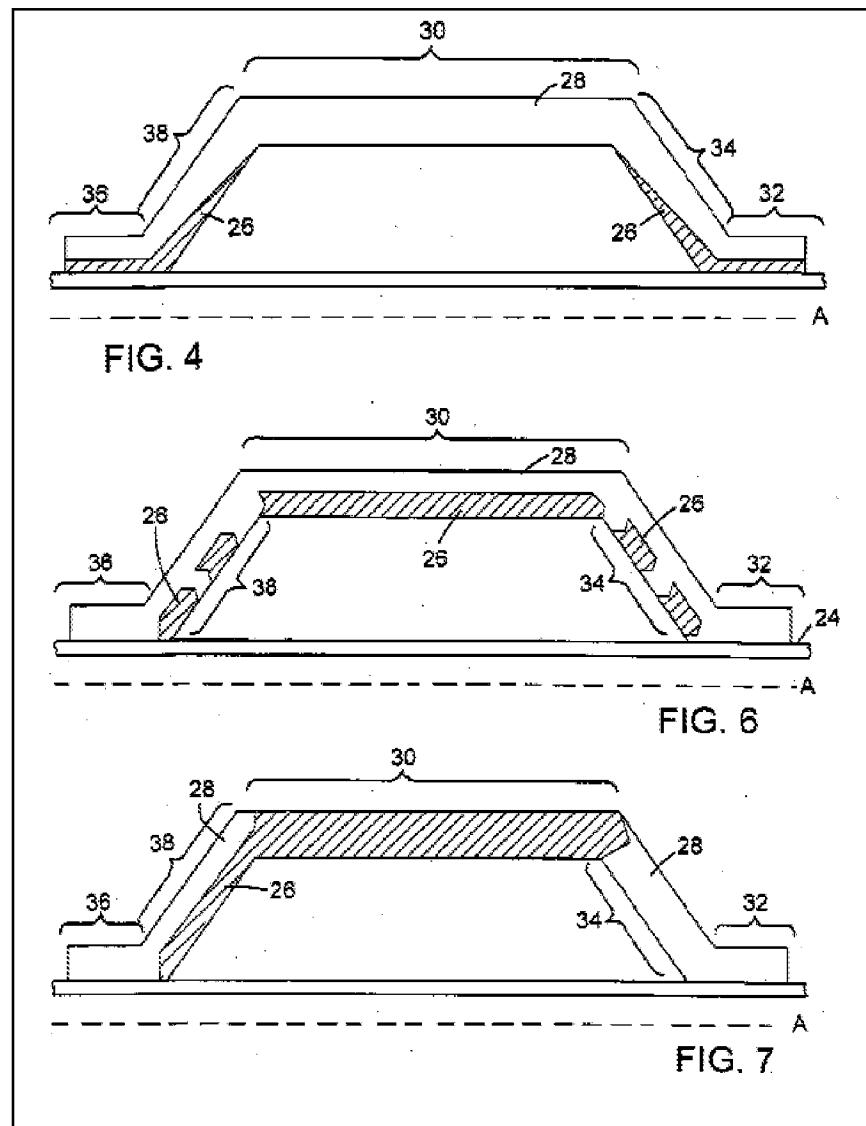
2. The following is an examiner's statement of reasons for allowance:  
3. The closest analogous prior art to applicants' disclosed invention is found in Devens, JR. et al. United States Patent Application No. 2005/0043679 (hereafter referred to as Devens).

4. Devens discloses a catheter balloon having varying stiffness down its length.

Devens achieves this by using different polymers in each layer of the balloon and varying the thickness of the layers. Devens also discloses that varying the flexibility of the balloon can be achieved by disposing different polymers in different regions of the balloon in different configurations as seen in figures 4 and 6-7. Although Devens

discloses that it is desirable for catheter balloons to display variable stiffness along their length, achieving this goal by varying the crystallinity of the polymers comprising the balloon is not disclosed.

Applicants' claims are specifically directed to a polymer material composition whereas the disclosure of Devens is directed to specific polymer layer configurations.



5. Sahatjian (U.S. 5,306,246) discloses adding a crystallization modifier to a polymer used for making a catheter balloon, but does not specifically disclose varying the concentration of the crystallization modifier along the length of the balloon.
6. Muni (U.S. 5,316,706) and Wang (U.S. 7,128,956) disclose catheters of variable polymer crystallinity down the length of the catheter tube. Neither of these patents discloses varying the crystallinity of the polymer along the length of a catheter balloon. The disclosed reasoning for varying the crystallinity of the polymers used in these patents is to control the flexibility of the catheter tubing portion in order to facilitate threading it through the tortuous venous networks of patients.
7. Although these patents are similarly directed towards the catheter art, the requirements of catheter tubing and catheter balloon material flexibility are quite different. Catheter tubing is required to be soft enough to not damage venous tissue and alternatively pliable and rigid enough to be threaded through vascular networks. Balloon catheters have different requirements for flexibility since they need to be able to be inflated to specific diameters under certain applied pressures but also need to be rigid and sturdy enough to not break.
8. The examiner feels it would be improper hindsight to combine the principle of variable crystallinity disclosed by Muni and Wang to Sahatjian or Devens since there is no clear motivation in the prior art or to those of ordinary skill in the art to vary the polymer crystallinity along the length of catheter balloons since the requirements for catheter tubing and balloon catheters are so different.

9. Regarding the recitation of "crystallization modifier amount is varied within the range of from 0 to about 20 percent by weight of the polymer composition" claimed in claim 2: The examiner clarifies that although the amount of crystallization modifier can be 0 in one section of the dilatation balloon, there must be crystallization modifier present in the balloon since the amount of crystallization modifier is specifically recited to vary in claim 1. If no modifier is present within the balloon anywhere, it cannot be said to vary.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE JACOBSON whose telephone number is (571)272-8905. The examiner can normally be reached on Monday-Friday 7:30 AM-5 PM EST (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, D. Lawrence Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. Lawrence Tarazano/  
Primary Examiner, Art Unit 4174

Michele L. Jacobson  
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